AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior versions, and listings, of claims in the present application.

LISTING OF CLAIMS:

1. (Currently Amended) An immunoassay for assaying target antigen or target antibody present in a serum component or a blood plasma component of a whole blood sample, comprising the steps of:

(a) mixing a whole blood sample with insoluble carrier particles which are sensitized with an antigen or antibody and have a different size than that of blood cells, to cause an immune agglutination reaction resulting in an immune agglutination reaction mixture comprising agglutinated insoluble carrier particles and unagglutinated insoluble carrier particles;

(b) introducing the immune agglutination reaction mixture to a flow cell, irradiating the particles passing through the flow cell with laser light, and detecting scattered lights generated thereby;

(c) setting a first threshold value for distinguishing unagglutinated insoluble carrier particles from agglutinated insoluble carrier particles and a second threshold value for distinguishing the agglutinated insoluble carrier particles from blood cells with regard to intensity of the scattered light; and

(d) distinguishing and counting the unagglutinated insoluble carrier particles, the agglutinated insoluble carrier particles and the blood cells from the intensity of the scattered lights detected in the step (b), in reference to the first and second threshold values set in the step (c), so as to assay the

target antigen or the target antibody present based on the counted agglutinated insoluble carrier particles.

2. (Previously Presented) The immunoassay according to claim 1, further comprising:

(e) calculating a degree of agglutination from the number of the unagglutinated insoluble carrier particles and the number of the agglutinated insoluble carrier particles, converting the degree of agglutination into the concentration of the target antigen or target antibody in the whole blood sample using a calibration curve showing a relationship between the degree of agglutination and the concentration of the target antigen or target antibody.

3. (Previously Presented) The immunoassay according to claim 2, further comprising:

(f) correcting the concentration of the target antigen or target antibody present in the whole blood sample according to the number of the blood cells.

4. (Previously Presented) The immunoassay according to claim 3, wherein the correction is made by use of the following formula:

$C = CO / (1 - B / A)$,

wherein C is a corrected value, CO is the concentration of the target antigen or target antibody present in the whole blood sample, B is the number of blood cells and A is a constant.

5. (Previously Presented) The immunoassay according to claim 1 or 2, further comprising:

(g) obtaining a mean corpusculer volume (MCV) in the whole blood sample, wherein the concentration of the target antigen or target antibody present in the whole blood sample is corrected according to the MCV measurement and the number of blood cells.

6. (Previously Presented) The immunoassay according to claim 5, wherein the mean corpusculer volume (MCV) is obtained from the scattered lights detected in the step (b), in reference to the threshold values set in the step (c).

7. (Previously Presented) The immunoassay according to claim 5, wherein correction according to the MCV measurement and the number of blood cells is made by use of the following formula:

$C = C0 / \{1 - (B/A) \times (MCV / D)\}$,

wherein C, C0, A and B are the same as defined above, MCV is the MCV measurement of the sample and D is a constant.

8. (Previously Presented) The immunoassay according to Claim 1, wherein the scattered light is forward scattered light.

9. (Previously Presented) The immunoassay according to Claim 1, wherein the size of the insoluble carrier particles is 0.1 μ m to 1.0 μ m.

10. (Previously Presented) The immunoassay according to Claim 1, wherein, in the step (a), the temperature is from 20 to 50°C and the time is from 15 seconds to 20 minutes.

11-12. (Canceled).

13. (Previously Presented) An immunoassay apparatus for assaying target antigen or target antibody present in a serum component or a blood plasma component of a whole blood sample, comprising:

a reaction part for mixing a whole blood sample with insoluble carrier particles which are sensitized with an antigen or antibody and have a different size than that of blood cells, to cause an immune agglutination reaction resulting in an immune agglutination reaction mixture comprising agglutinated insoluble carrier particles and unagglutinated insoluble carrier particles;

a dispensing mechanism for introducing the resulting immune agglutination reaction mixture to a flow cell,

a laser for irradiating the particles passing through the flow cell with laser light,

a photo acceptance unit for detecting scattered light generated thereby,

signal processing means for converting the scattered light to an electrical signal, and

data processing means for setting a first threshold value for distinguishing unagglutinated insoluble carrier particles from agglutinated insoluble carrier particles and a second threshold value for distinguishing the agglutinated insoluble carrier particles from blood cells with regard to signal based on intensity of the scattered light; and for distinguishing and counting the unagglutinated

insoluble carrier particles, the agglutinated insoluble carrier particles and the blood cells according to the set first and second threshold values.

14. (Previously Presented) The immunoassay apparatus according to Claim 13, further comprising:

calculating means for calculating a degree of agglutination from the number of the unagglutinated insoluble carrier particles and the number of the agglutinated insoluble carrier particles, converting the degree of agglutination into the concentration of a target antigen or target antibody in the whole blood sample using a calibration curve showing a relationship between the degree of agglutination and the concentration of the target antigen or target antibody; and correcting the concentration of the target antigen or target antibody according to the number of the blood cells.